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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,108	06/24/2003	Gary L. Breton	PATH03-14	2547
23856	7590	10/29/2007		
OSCIENT PHARMACEUTICALS CORPORATION 1000 WINTER STREET Suite 2200 WALTHAM, MA 02451			EXAMINER ZHOU, SHUBO	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 10/29/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/603,108

Applicant(s)

BRETON, GARY L.

Examiner

Shubo (Joe) Zhou

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: sequence alignment.

### **DETAILED ACTION**

Applicant's amendment and request for reconsideration filed 8/8/07 are acknowledged and the amendment is entered.

Claims 1-9 are currently pending and under examination.

Applicant's arguments in response to the previous Office action have been fully considered but they are not deemed to be completely persuasive. The following rejections and/or objections are either reiterated from the previous Office action or newly applied but necessitated by applicant's amendment and constitute the complete set presently being applied to the instant application. Rejections and/or objections not reiterated from the previous Office action are hereby withdrawn.

#### ***Claim Rejections-35 USC § 101 and § 112***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

This rejection is reiterated from the previous Office action.

Claims 1-9 are drawn to nucleic acids having a nucleotide sequence of SEQ ID NO: 1298 or a sequence encoding the amino acid sequence of SEQ ID NO:3218, or recombinant vectors

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comprising the nucleic acid or cells comprising the recombinant vectors. The claimed nucleic acid is not supported by a specific asserted utility because none of the disclosed uses of the nucleic acid in the specification is specific and substantial. For example, the specification throughout states that the nucleic acids disclosed can be used as a probe for diagnosis of *M. catarrhalis* bacteria or diseases caused thereby. However, the use is not specific to the nucleic acid of SEQ ID NO:1298 but generic to thousands of sequences of SEQ ID NOs:1-1920. Furthermore, it would be readily recognized by one skilled in the art that for a nucleic acid to be used as a probe for diagnosis of the bacterium *M. catarrhalis* or diseases caused thereby, the nucleic acid has to be specific only to *M. catarrhalis*, without cross-hybridization to other organisms. However, this is hardly the case for the sequence of SEQ ID NO:1298. Wedler et al. disclose a yeast nucleic acid sequence (GenBank accession number Z72861) that contains a sequence that is identical to a stretch of 21 consecutive nucleotides of SEQ ID NO:1298. See the attached sequence alignment between SEQ ID NO:1298 and Z72861, the result of an oligomer search. It would be readily apparent to one skilled in the art that such a sequence with 21 consecutive nucleotides identical to that stretch of the instant SEQ ID NO:1298 would cross-hybridize to the latter under relatively low stringency and even under high stringencies. Thus, using the sequence as a probe would have cross-hybridization to sequences of other organisms even under stringent conditions. It would require further research to determine a specific sequence, if any, for *M. catarrhalis* that is unique only to the organism so that it would be able to be used as a probe for diagnosis for *M. catarrhalis*. Recently, in *In re Fisher*, a case analogous to the present application, the court, following an analysis of Nelson, 626 F.2d at 856, with regard to substantial utility, states that “it thus is clear that an application must show that an invention is

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useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research.” *In re Fisher*, 76 USPQ2d 1225 1230 (CAFC 2005). In the instant case, the application does not show that the claimed polynucleotide is useful as a probe for the diagnosis of *M. catarrhalis* to the public as disclosed in its current form, but that it may prove useful at some future date after further research.

Additionally, neither the specification as filed nor any art of record discloses or suggests any property or activity for the polypeptide encoded by SEQ ID NO:1298 such that another non-asserted utility would be well established for the claimed nucleic acid.

Applicant’s arguments filed 8/8/07 has been fully considered but they are not persuasive. Applicant first cite the MPEP regarding research tools such as sequencing techniques and argues that nucleotide sequencing techniques can meet the utility requirement under 35 USC 101 if the nucleic acid sequences and the proteins encoded thereby have specific, substantial and credible utilities. See page 6 of the response. This is confusing and unpersuasive because the claims are not drawn to nucleotide sequencing technique.

Applicant then cites the MPEP regarding well-established utility and argues that “one or more well-established utilities would be readily apparent to one of skill in the art. In particular, one of skill in the art would recognize and appreciate the utility of the claimed invention for the purposes of developing new drug targets, diagnostics and therapeutics.” See page 7 of the response. This is not found persuasive because using the claimed nucleic acid for the purpose of developing new drug targets, diagnostics and therapeutics is not a substantial utility but simply an invitation for further experimentation. As set forth above, the court, in *In re Fisher*, holds that “it thus is clear that an application must show that an invention is useful to the public as

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disclosed in its current form, not that it may prove useful at some future date after further research.” Using the nucleic acid for searching drugs, diagnostics and therapeutics, etc., does not show that the claimed polynucleotide is useful to the public as disclosed in its current form, but that it may prove useful at some future date after further research.

Applicant also cites Moir et al., Smith, etc. and argues that the nucleic acid can be used to identify therapeutics, etc. Again, this utility is not found to be a substantial utility because it is a mere invitation for further research. There is no reasonable expectation for success of obtaining such a therapeutics because what is disclosed and used in Moir et al. is different from what is claimed.

Applicant then states that the specification provides the identified nucleic acid sequence homology, thereby providing strong support for the function of the claimed protein and that Table 2 provides that the amino acid sequence SEQ ID NO:3218, encoded by nucleic acid sequence SEQ ID NO:1298, asserts homology with H. influenzae acetylglucosamine-1-phosphate uridyltransferase, an essential protein in the synthetic pathway of H. influenzae. This is also found unpersuasive. Firstly, it is noted that Table 2 of the specification does not indicate percentage of the homology between the two proteins. A search by the Office indicates that the overall match between the two proteins is 51.8%. See the attached sequence alignment between the two proteins. Secondly, it would have been well known in the art that sequence similarity does not reliably correlate to sequence similarity and that sequence similarity does not reliably result in similar or identical biological activities. For example, it would have been well known that even a single nucleotide or amino acid change or mutation is able to destroy the function of the biomolecule in many instances, albeit not in all cases. In the absence of factual evidence

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characterizing the structural and functional components of the biomolecule, the effects of these changes are largely unpredictable as to which ones will have a significant effect and which ones will be silent mutations having no effect. Therefore, without experimental evidence, purely based on sequence homologies, one skilled in the art would have reasonable doubt that the claimed nucleic acid encodes acetylglucosamine-1-phosphate uridylyltransferase, and would have to perform further research to verify such and to determine a utility for the real protein it encodes. The apparent need for such further research to determine a practical utility for the claimed nucleic acid indicates that the claimed invention does not have a readily available utility.

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention lacks a patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

This rejection is reiterated from the previous Office action and maintained for reasons set forth above.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.**

Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the



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/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

*PRIMARY EXAMINER*

# Attachment: Sequence Alignment

G64083

glmU protein homolog - Haemophilus influenzae (strain Rd KW20)

C;Species: Haemophilus influenzae

C;Date: 18-Aug-1995 #sequence\_revision 18-Aug-1995 #text\_change 09-Jul-2004

C;Accession: G64083

R;Fleischmann, R.D.; Adams, M.D.; White, O.; Clayton, R.A.; Kirkness, E.F.; Kerlavage, A.R.; Bult, C.J.; Tomb, J.F.; Dougherty, B.A.; Merrick, J.M.; McKenney, K.; Sutton, G.; FitzHugh, W.; Fields, C.; Gocayne, J.D.; Scott, J.; Shirley, R.; Liu, L.I.; Glodek, A.; Kelley, J.M.; Weidman, J.F.; Phillips, C.A.; Spriggs, T.; Hedblom, E.; Cotton, M.D.; Utterback, T.R.; Hanna, M.C.; Nguyen, D.T.; Saudek, D.M.; Brandon, R.C.; Fine, L.D.; Fritchman, J.L.; Fuhrmann, J.L.; Geoghagen, N.S.M.

Science 269, 496-512, 1995

A;Authors: Gnehm, C.L.; McDonald, L.A.; Small, K.V.; Fraser, C.M.; Smith, H.O.; Venter, J.C.

A;Title: Whole-genome random sequencing and assembly of Haemophilus influenzae Rd.

A;Reference number: A64000; MUID:95350630; PMID:7542800

A;Accession: G64083

A;Status: nucleic acid sequence not shown; translation not shown

A;Molecule type: DNA

A;Residues: 1-456 <TIGR>

A;Cross-references: UNIPROT:P43889; UNIPARC:UPI000012B68B; GB:U32747;

GB:L42023; NID:g1573635; PIDN:AAC22302.1; PID:g1573640; TIGR:HI0642

C;Superfamily: N-acetylglucosamine-1-phosphate uridyltransferase

Query Match 51.8%; Score 877; DB 2; Length 456;  
Best Local Similarity 52.0%; Pred. No. 8e-58;  
Matches 171; Conservative 52; Mismatches 106; Indels 0; Gaps 0;

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Qy      1 MLTLTVDKPFGGLGRIVRNQGVVAIVREKADTQQKLITEINSGIYCVDNALLHKYLPIL 60
      :||: :| | | |||:| | |||| :||: :| | |:|:|: | | |:| :
Db      128 LLTVNLDNPTGYGRIIRENGNVVAIVEQKDANAEQLNIKEVNTGVMVSDGASFKKWLARV 187

Qy      61 NNNNAQGEYYLTDIIKLAVDDGVEIVTIEPKFAFEIEGVNDRIQLANLERDFQSHQIHQL 120
      ||||| |||||:| || | :|| :| :|| |:| || | || |:| | :|
Db      188 GNNNAQGEYYLTDLIALANQDNCQVVAVQATDVMEVEGANNRLQLAALERYFQNKQASKL 247

Qy      121 QIAGVQFADPNRVDIRGKLTCDRDVFIDINTVFVGDVHLGMGVQIDAGNVITNSHIGNQT 180
      : || | | |:| | | :|| ||:| : |:| || |:| | |:| | ||
Db      248 LLEGVMIYDPAFRLRGTLHGKDVEIDVNVIIEGNVKLGDRVKIGTGCVLKNVVIGNDV 307

Qy      181 HIKPNCVIDDSMIGQNVSIGPFAHIRPKTILSDVKIGNFVETKKTTVGVGSKINHLSYA 240
      ||| |:| |:| |:| : ||||: || |: : :||| ||: ||| |:| |:|
Db      308 EIKPYSVLEDSIVGEKAAIGPFSRLRPGAELAAETHVGNFVEIKKSTVGKGSKNHLYV 367

Qy      241 GDSIIQNVNIGAGVITCNVDGINKFTTTIGDRAFIGSNSSLVAPVTVGMGATIGAGSVI 300
      ||| || | ||||| ||||| ||| | || |:| |:| |||| | ||||| |:|
Db      368 GDSEIGSNCNIGAGVITCNVDGANKFKTIIGDDVFVGSDTQLVAPVKVANGATIGAGTTI 427

Qy      301 TKDAKDNALTLARAKQATIIGWSRPKKNQ 329
      |:| :| | :| | | | || || | :
Db      428 TRDVGENELVITRVAQRHIQGWQRPIKKK 456
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